

## Structured Product Labeling (SPL) OTC Sub-team Teleconference

Call-in details: Dial [215-446-3649](tel:215-446-3649); Enter Access Code [5222603#](#)

*(Call 202-429-9260 if there are problems accessing the teleconference.)*

Monday, April 11, 2011, 1:00 pm – 2:00 pm ET (call to start promptly at 1:00 pm ET)

Agenda (as of April 7, 2011 – subject to change)

- I. **Welcome and Introductions** 1:00 pm
  - Attendance taken via email (sent to Marcia Howard)
- II. **Next Standing Teleconference:** May 9, 2011 (unless cancelled)
  - Standing calls for 2011 will be held on the second Monday of each month at 1:00 pm ET.
  - Calls will no longer be scheduled on the fourth Monday of the month.
- III. **Discussion** 1:00 – 1:45 pm
  - A. Debrief on ER/DL Call with FDA staff
  - B. Open Discussion
- IV. **SPL Educational Forums/Information** *(For Your Information)*
  - A. FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>  
  
Please visit the SPL Wiki page to access training materials (<http://spl-work-group.wikispaces.com/>)
  - B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ER/DL calls)  
Telephone number: 877-423-2663  
PIN#: 5240184  
Please email Process Team co-leaders Terry Brunone ([Theresa.M.Brunone@gsk.com](mailto:Theresa.M.Brunone@gsk.com)) or Mary Beth Wilusz ([mary\\_beth\\_wilusz@merck.com](mailto:mary_beth_wilusz@merck.com)) if you want to get the email information.

C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover ([COWALL-HANOVER.PATRICIA.L@LILLY.COM](mailto:COWALL-HANOVER.PATRICIA.L@LILLY.COM)) or Jessica Dunn Skorupski if you want to get the email information ([JSkorups@its.jnj.com](mailto:JSkorups@its.jnj.com)).

D. **SPL Generics Sub-team calls:** Not currently holding regular calls. Please email sub-team leader Virginia Hogan if you want to get the email information ([Virginia.Hogan@tevausa.com](mailto:Virginia.Hogan@tevausa.com)).

E. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST. Please email Sub-team leader Myron Finseth ([myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com)) if you want to join this sub-team.

Telephone Number: 770-657-9270  
Participant passcode: 745896

F. **SPL Usage Discussion Group**  
Please email or call Terry Brunone ([Theresa.M.Brunone@gsk.com](mailto:Theresa.M.Brunone@gsk.com); +1-215-751-3210) or Gary Saner ([gsaner@reedtech.com](mailto:gsaner@reedtech.com); +1-610-731-7192) if you wish to join the discussion group.

G. **Homeopathic Sub-team** (*new sub-team; not replacing SPL OTC sub-team*)  
Contact sub-team leader Travis Borchardt ([tborchardt@enzy.com](mailto:tborchardt@enzy.com)) if you wish to join this sub-team.

H. Other training opportunities???

V. **Adjourn**

1:55 pm

MDH/04-07-11

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Last Revised: April 7, 2011 Sent: April 7, 2011